

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

LIGHTCARE RX, LLC,

Plaintiff

V.

TEXAS STATE BOARD OF PHARMACY,

Defendant

CASE NO. 4:21-cv-02240

COMPLAINT

Plaintiff LightCare Rx, LLC (“Plaintiff LightCare”), by counsel, respectfully files this action for declaratory judgment to declare Texas state regulation 22 TAC §291.11 as unconstitutional and preempted by federal Medicare and Medicaid laws and regulations. For its complaint against Defendant Texas State Board of Pharmacy (“Defendant TXSBP”), Plaintiff LightCare alleges as follows:

I. INTRODUCTION

1. Plaintiff LightCare challenges the constitutionality of Defendant TXSBP’s regulation 22 TAC §291.11 that arbitrarily requires a new pharmacy to fill an unspecified number of scripts within the first six months of operations, or face serious penalties, disciplinary action, and financial ruin.
2. As applied, 22 TAC 291.11 discriminates between residents of Harris County (a federally designated H.E.A.T Zone area) and other non-H.E.A.T designated areas of Texas because Harris County and surrounding area residents require substantially more than six (6) months to obtain the proper credentialing from Medicare, Medicaid, and insurance companies that

administer the various federal healthcare programs. Because residents of counties other than Harris County do not face similar punitive sanctions, 22 TAC 291.11 violates the Equal Protection Clause of the United States Constitution.

3. Harris County (and certain parts of Fort Bend, Washington, and Brazoria counties) is designated a “H.E.A.T.” zone by the Drug Enforcement Agency (“DEA”) and upon information the U.S. Department of Health & Human Services (“HHS”).
4. Pharmacies (such as Plaintiff) in H.E.A.T zone areas currently require more than six months to receive credentialing from Medicare, Medicaid, and various insurance companies that administer the various Medicare and Medicaid programs. Other counties in Texas that are not designated as H.E.A.T zone areas can complete the necessary paperwork within sixty (60) days.
5. These H.E.A.T zone expanded requirements make what is generally a straightforward and simple application process into a complex, arduous experience. H.E.A.T. Zone pharmacies interested in joining a PBM and insurance networks must now complete significantly longer credentialing documentation, with the additional pages concerning attestation of legal operations.
6. Defendant TXSBP’s regulation 22 TAC 291.11 is an arbitrary rule that fails to consider the impact of the H.E.A.T. designation on pharmacies such as Plaintiff LightCare. Moreover 22 TAC 291.11, which requires an unspecified number of scripts be filled, allows Defendant TXSBP to impose sanctions arbitrarily, discriminatorily, and abusively upon Pharmacies such as Plaintiff without any specific standard.
7. Further, 22 TAC 291.11 is preempted by Federal Medicare, Medicaid, and DEA regulations which require a pharmacy in H.E.A.T. zone areas to undergo rigorous credentialing process

that currently exceed six (6) months. Nothing under Medicare and Medicaid laws and regulations require that a Pharmacy to fill an unspecified and arbitrary and undefined number of scripts or require a pharmacy to an unidentified number of scripts within six months. Because Medicare and Medicaid require a pharmacy to be in good standing and without any disciplinary history, 22 TAC 291.11 impermissibly interferes with Medicare and Medicaid credentialing requirements.

8. Since Defendant TXSBP is uninterested in the difficulties facing pharmacies in H.E.A.T zone areas, and because a disciplinary note on a pharmacy's record is grounds for termination from Medicare, Medicaid, and other private insurance companies that administer various federal programs, LightCare has suffered a cognizable injury that can only be addressed by a judgment declaring 22 TAC §291.11 unconstitutional and preempted by Federal law.

II. JURISDICTION & VENUE

9. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §1331 as the issues herein involve questions of federal law (Medicare and Medicaid), and the Equal Protection Clause and Commerce Clause of the United States Constitution.
10. Venue is proper pursuant to 28 U.S.C. §1391 because all events arising out of this matter occurred in the Southern District of Texas, in Harris County, TX.

III. THE PARTIES

11. Plaintiff LightCare Rx, LLC ("Plaintiff LightCare") is a Texas limited liability company engaged in the business of retail pharmacy.

12. Defendant Texas State Board of Pharmacy (“Defendant TXSBP”) is a Texas state agency that administers and regulates the practice of pharmacy in the State of Texas. Defendant TXSBP may be served by serving a copy upon its legal counsel at 333 Guadalupe St. #3, Austin, TX 78701, and the Texas Attorney General’s Office at Texas Attorney General 6161 Savoy Dr. #320, Houston, TX 77036, and Office of the Attorney General of Texas at 300 W. 15th St. Austin, TX 78701.

IV. STATEMENT OF CLAIM

13. On November 19, 2018, Plaintiff LightCare was incorporated as a Texas limited liability company to operate a retail pharmacy.
14. Between November 19, 2018, and April 19, 2019, Plaintiff invested substantial capital to develop, build-out, install, and ready its pharmacy for retail operations.
15. On April 19, 2019, an agent of Defendant TXSBP inspected LightCare pharmacy for purposes of issuing a Class A retail pharmacy license. After a thorough inspection, the Pharmacy was approved, and a license was issued.
16. On April 26, 2019, a Class A retail pharmacy license was issued for Plaintiff LightCare Rx, LLC. The Pharmacy promptly opened, was well stocked with inventory, supplies, and equipment, and ready to dispense prescriptions to the public.
17. In early May 2019, Plaintiff LightCare began preparing all applications necessary to obtain a National Provider Identifier (NPI), National Council for Prescription Drug Programs (NCPD) number, and a Drug Enforcement Agency (“DEA”) registration number.
18. Without the NPI, NCPDP, and DEA registration numbers, Plaintiff LightCare was not unable to apply for credentialing with Medicare, Medicaid, and insurance companies that administer Medicare and Medicaid programs as a network member.

19. In June 2019, the DEA Houston office advised Plaintiff that Harris County was designated a “H.E.A.T”¹ zone area. In so doing, the DEA required Plaintiff to undergo a long and rigorous credentialing process that was never before required of pharmacies in the Harris County area. Thus, what used to take a week to obtain a DEA registration number can now require at least 2 months.
20. The DEA does not require the same process of pharmacies in rural areas, and cities and towns in Texas that are not designated as a H.E.A.T Zone.
21. On August 19, 2019, the DEA issued Plaintiff a DEA registration number. It was only after that date that Plaintiff LightCare was able to start to apply to become a member of PBM networks that administer the various Medicare and Medicaid programs.
22. However, at all times Plaintiff was open to the public to fill scripts. In fact, several customers presented scripts to be filled. But because these customers were all insured under various federal healthcare programs, they refused to pay in cash for their prescriptions when Plaintiff advised them that pharmacy was still awaiting to be approved for credentialing.
23. Aside of the DEA’s new regulations and rigorous credentialing, every insurance company, pharmacy benefit manager, including Medicare and Medicaid have implemented rigorous credentialing process for areas designated as H.E.A.T. Zones.

B. Defendant TXSBP’s Pharmacy Inspection

24. On February 2, 2020, the TXSBP again inspected Plaintiff LightCare as part of a routine inspection. An agent of the TXSBP, despite noting that the pharmacy is open to the public, was well-stocked with inventory and equipment, decided without merit that Plaintiff violated

¹ Health Care Fraud Prevention and Enforcement Action Team

22 TAC §291.11 for not filling sufficient number of scripts. However, 22 TAC §291.11 does not expressly provide a number of specific scripts to be filled.

25. In fact, Plaintiff had already filled one script, attempted to fill many other scripts but was unable because it was awaiting credentialing from insurance companies that administer Medicaid and Medicare programs.
26. When Plaintiff informed Defendant's agent that a script was filled, and that other scripts were submitted for processing but were awaiting credentialing delays, Defendant's agent simply pointed to 22 TAC §291.11 that requires a "sufficient" number of scripts to be filled, **without specifying how many scripts** needed to be filled, and without considering the fact that prescriptions were already submitted for processing but because of no fault of the Pharmacy could not be processed pending credentialing by PBMs that administer the various federal healthcare programs, including Medicare and Medicaid.
27. Plaintiff further explained to Defendant that numerous Medicaid and Medicare patients came to the pharmacy to fill their scripts but refused to pay cash.
28. Plaintiff's customers are entitled to have their prescriptions processed by the various federal healthcare programs that are administered by PBMs.
29. In March 2020, Plaintiff was approved for several PBMs and Medicaid, and has since processed hundreds of scripts for insured patients without incident. To this date, not one cash paying patient has elected to pay for his or her prescription.
30. Notwithstanding all of the above, Defendant TXSBP began disciplinary proceedings alleging that Plaintiff did not fill sufficient number of scripts during the first six months.
31. Defendant made this ridiculous finding despite knowing fully that the Pharmacy was open, received scripts from patients but was not able to process the scripts due to credentialing

delays from various federal healthcare benefit programs and private insurance companies that administer these programs.

32. Defendant TXSBP ignored and discriminated against Plaintiff LightCare which is located in a H.E.A.T zone area, unlike pharmacies in other counties in Texas who do not face similar issues and delays and are not at risk of facing adverse disciplinary issues that may impact their credentialing applications with federal healthcare programs.

33. Last but not least, 22 TAC 291.11, contravenes the express language of the Texas Pharmacy Act (“TPA”), which contains no requirement that scripts be filled within any time period.

V. CAUSES OF ACTION

FIRST CAUSE OF ACTION

VIOLATION OF THE EQUAL PROTECTION CLAUSE (“EPC”)

34. The above paragraphs are reincorporated herein.

35. The Equal Protection Clause (“EPC”) states that "nor shall any State ... deny to any person within its jurisdiction the equal protection of the laws". The EPC mandates that individuals in similar situations be treated equally by the law.

36. The TXSBP through its application of TAC §291.11 discriminates against Plaintiff, a resident of Harris County (a H.E.A.T designated zone), by requiring Plaintiff to fill an unknown number of scripts within six months of licensing without any consideration for the difficulties and serious delays Plaintiff LightCare faced as resident of a Harris County.

37. Defendant TXSBP further refuses to acknowledge the prolonged credentialing requirements of federal healthcare programs, including the DEA registration requirements.

38. Pharmacies in non-HEAT zones can process all required licensing matters within 60 days giving them sufficient time to obtain all insurance, Medicare, and Medicaid credentialing to operate their retail pharmacy, and accept patients enrolled in these programs.
39. Plaintiff's customers cannot be forced to pay cash in contravention of Medicaid and Medicare laws because of Defendant's ill-conceived, ambiguous, discriminatory, arbitrary, and ultimately unconstitutional regulation, which without basis demands that a Pharmacy must fill some number of scripts without specifying how many, and without regard for the requirements of federal healthcare programs.
40. Accordingly, 22 TAC §291.11 directly discriminates against Plaintiff who is a resident of Harris County (a H.E.A.T zone area), and residents of other counties who are able to successfully and quickly obtain credentialing.

SECOND CAUSE OF ACTION

VIOLATION OF FREEDOM OF ASSOCIATION CLAUSE

41. The above paragraphs are reincorporated herein.
42. Freedom of Association encompasses both an individual's right to join or leave groups voluntarily and includes rights of individuals coming together with other individuals to collectively express, promote, pursue and/or defend common interests.
43. Plaintiff has numerous Harris County Medicaid and Medicare customers who wish to conduct business with Plaintiff, including receiving prescription drug counseling, personal attention, and home delivery of their needed prescription.
44. Section §291.11 of Title 22 imposes draconian fines and ruinous disciplinary record upon Plaintiff (and pharmacies similarly situated) when Plaintiff's customers refuse to pay cash for

their prescriptions that Defendant's regulation that requires an unspecified amount be filled within six months.

45. Accordingly, TAC §291.11 is unconstitutional as it violates Plaintiff's customers' Freedom of Association right under the U.S. Constitution.

**THIRD CAUSE OF ACTION
VIOLATION OF MEDICARE PROVIDER ENROLLMENT
REQUIREMENTS**

46. The above paragraphs are reincorporated herein.
47. Pursuant to 42 CFR § 424.510, a provider undergoes rigorous requirements for enrollment. These requirements require more than six months, and require that a provider to be licensed, and without any disciplinary record. If a provider has any disciplinary action on their record, this will cause either termination from Medicare, or delay even more credentialing with Medicare programs.
48. Defendant TXSBP was notified that its application of TAC 291.11 to require an unknown number of scripts to be filled within six months is not only discriminatory against Pharmacies in H.E.A.T. zone areas, but also causes serious harm to pharmacies awaiting delayed Medicare and Medicaid credentialing because any disciplinary action would preclude the applying pharmacy from approval into federal healthcare programs, and the networks of insurance companies that administer various federal healthcare programs.
49. Defendant TXSBP continues to ignore that its discriminatory and unlawful application of TAC §291.11 directly interferes with Plaintiff's ability to credential with insurance companies and PBMs that administer Medicare and Medicaid programs.

50. It is well established that Medicare and Medicaid are federal programs, and that such programs may not be preempted by state laws, unless expressly agreed to by Congress.
51. Nothing under Medicare and Medicaid regulation permit Defendant TXSBP to enact regulations that burden Plaintiff's right to credential timely and properly with the various Medicare and Medicaid programs.
52. Accordingly, 22 TAC §291.11 is preempted by 42 CFR § 424.510 and any other Medicare and Medicaid credentialing requirements.

VI. RELIEF REQUESTED

Wherefore, Plaintiff respectfully requests judgment declaring 22 TAC §291.11 as unconstitutional, unenforceable, and pre-empted by federal law. Further, Plaintiff requests attorneys' fees and court costs, and any other relief that court deems just and proper.

Date: July 9, 2021

Respectfully Submitted,

DEWOOD, P.C.

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